

UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandra, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/620,331	07/20/2000	Kimberly R. Gamble	ML-02C 2749	
7	590 07/02/2003			
Kenneth S Watkins Jr			EXAMINER	
372 River Driv Dahlonega, GA	_		QUAN, ELIZ	ABETH S
			ART UNIT	PAPER NUMBER
			1743	17
			DATE MAILED: 07/02/2003	10

Please find below and/or attached an Office communication concerning this application or proceeding.

		B				
•	Application No.	Applicant(s)				
Office Action Summany	09/620,331	GAMBLE ET AL.				
Office Action Summary	Examiner	Art Unit				
TI WALL DIS DATE OUT	Elizabeth Quan	1743				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
1) Responsive to communication(s) filed on 27.	<u>lanuary 2003</u> .					
2a)⊠ This action is FINAL . 2b)□ Th	is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims						
4)⊠ Claim(s) <u>1-32</u> is/are pending in the application.						
4a) Of the above claim(s) <u>1-9 and 14-16</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>10-13 and 17-32</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement. Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a)☐ All b)☐ Some * c)☐ None of:						
 Certified copies of the priority documents have been received. 						
2. Certified copies of the priority documents have been received in Application No						
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Inform	ary (PTO-413) Paper No(s) al Patent Application (PTO-152)				
J.S. Patent and Trademark Office						

Application/Control Number: 09/620,331 Page 2

Art Unit: 1743

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 10-13, 17-20, 32 are rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention.

3. Referring to claim 10, the claim fails acknowledge that both the sample chamber as well

as the area defined by the boundaries provided by the seal surface of the insert, reduced-diameter

portion, and bottom portion of the vessel together dined a reduced-volume sample chamber as

described in the specification.

4. Claim 13 recites the limitation "the through-chamber" in the second line. There is

insufficient antecedent basis for this limitation in the claim.

5. Claim 19 recites the limitation "the sample insert" in the second line. There is

insufficient antecedent basis for this limitation in the claim.

6. Referring to claim 32, Applicant should label the septum seals--first septum seal and

second septum seal--as "the septum seal" in the second to the last line of the claim does not

specify which septum seal it is. There is antecedent basis problem in regard to that. Also, "a

penetrating" in the third line should be "the penetrating."

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Application/Control Number: 09/620,331 Page 3

Art Unit: 1743

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10, 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,567,309 to Classon et al.

Referring to claims 10, 21-25, Classon et al. disclose a method of testing samples. A volume-adjusting insert (12), which comprises a top and bottom defining an axial direction, septum seal (37) in the upper portion, reduced-diameter portion (76) communicating with a bottom end of the insert between the septum seal (37) and the bottom end of the insert, conical guide (74) disposed between the septum seal (37) and reduced diameter portion (76), and seal surface (36) with sealing ridges (39,84) on the outer surface of the insert for sealing an inside seal surface of the sample vessel (100), is inserted into a sample vessel (100) (see FIGS. 8-10; COL. 8, lines 51-67; COL. 9; COL. 10, lines 1-22). The seal surface (36) along with its sealing ridges (39,84), reduced diameter portion (76) and a bottom portion of the vessel (100) define a reduced-volume sample chamber compared to the volume of the sample vessel (100) whether or not the volume of the reduced diameter portion (76) is accounted in the volume (see FIGS. 8-10). A penetrating sample deposit/extraction element (86) is positioned above the septum seal (37) of the insert (12) and inserted through the septum seal (37) and conical guide (74) and into reduced-diameter portion (76) to a depth sufficient to provide axial alignment of the insert (12) and the sample deposit/extraction element (86) (see FIGS. 8-10; COL. 8, lines 4-33; COL. 9, lines 11-23). A sample fluid is transferred among the sample deposit/extraction element (86) and reduced-volume sample chamber, which is defined

Application/Control Number: 09/620,331 Page 4

Art Unit: 1743

by the bottom portion of the vessel (100) (see FIGS. 8-10; COL. 7, lines 57-66; COL. 8, lines 1-50; COL. 9; COL. 10, lines 1-21). A processing element (24) is disposed in the bottom portion of the insert (12), and the sample fluid is transferred through the processing element (24) by the sample deposit/extraction element (86) (see FIGS. 8-10; COL. 4, lines 36-42; COL. 6, lines 11-27; COL. 8, lines 4-50). The processing element may be an adsorbent element as it may be directed to chromatography or extraction and/or absorbent element as the element sucks and holds liquid, specifically a filter (see COL. 4, lines 35-42; COL. 6, lines 11-27). Therefore, Classon et al. include all the limitations of claims 10, 21-25.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Application/Control Number: 09/620,331

Art Unit: 1743

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 11 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,567,309 to Classon et al.

Referring to claims 11 and 26, Classon et al. disclose the steps of positioning and inserting a volume-adjusting insert (12) into a sample vessel (100), positioning a penetrating sample deposit/extraction element (86) above the insert (12), and inserting the penetrating sample deposit/extraction element (86) through the septum seal (37) and conical guide (74) and into the reduced-diameter portion (76) (see FIGS. 8-10; COL. 8, lines 4-67; COL. 9, lines 1-23). The positioning and process of inserting of the insert (12) into the vessel (100) is accomplished with the sample deposit/extraction element (86) through frictional engagement of the sample deposit/extraction element (86) and septum seal (37) (see FIGS. 8-10; COL. 7, lines 41-67; COL. 8, lines 1-50; COL. 9, lines 4-23). Classon et al. do not explicitly disclose performing the steps of positioning and inserting the penetrating sample deposit/extraction element into the insert before the steps of positioning and inserting the insert into the sample vessel such that the sample deposit/extraction element is required to position and insert the insert into the vessel. Applicant has not disclose that positioning and inserting the penetrating sample deposit/extraction element into the insert before positioning and inserting a volume-

adjusting insert into the sample vessel solves any stated problem or is form any particular purpose. Moreover, it appears that the method would yield the same results no matter what the order of steps is performed. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method Classon et al. to insert the penetrating sample deposit/extraction element into the insert prior to position and inserting the insert into the sample vessel since it has been held that a reversal of method steps involves only routine skill in the art (*In re Einstein*, 8 USPQ 167).

7. Claims 12, 13, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,567,309 to Classon et al. in view of U.S. Patent No. 6,083, 761 to Kedar et al. and/or U.S. Patent No. 4,787,971 to Donald.

Referring to claims 12 and 13, Classon et al. disclose using hydraulic pressure generated by the penetrating sample deposit/extraction device (86) to transport the sample fluid through the through-chamber (67,68) (see FIGS. 4-7; Col. 8, lines 4-25). Furthermore, the sample fluid is passed through a processing element (24) (see FIGS. 4-7; COL. 17-38). Classon et al. disclose a processing element (24) that is disposed in the bottom portion of the insert (12), and the sample fluid is transferred through the processing element (24) by the sample deposit/extraction element (86) (see FIGS. 8-10; COL. 4, lines 36-42; COL. 6, lines 11-27; COL. 8, lines 4-50). The processing element may be an adsorbent element as it may be directed to chromatography or extraction and/or absorbent element as the element sucks and holds liquid, specifically a filter (see COL. 4, lines 35-42; COL. 6, lines 11-27). Classon et al. do not disclose a sample well

with a bottom-extraction opening. However, multi-well plates with wells having a hole at the bottom are well known accessory equipment for solid phase extraction and draining of wastes as provided in Kedar et al. and Donald. Kedar et al. disclose a capillary hole (34) at the bottom of (28) of each well (28) of the plate (12) (see ABSTRACT; FIGS. 3-10; COL. 8, lines 51-42; COL. 13, lines 6-67; COL. 14, lines 1-48). Extrinsic forces, such as applying a vacuum, centrifuging, or using an absorbent material, are required to drain liquids from the wells (see ABSTRACT; FIGS. 3-10; COL. 8, lines 51-42; COL. 13, lines 6-67; COL. 14, lines 1-48). Since these extrinsic forces would disrupt the liquid, liquid or hydraulic force is inherently present. According to Merriam-Webster Collegiate Dictionary, hydraulic is defined as of or relating to water or other liquid in motion or operated by the resistance offered or the pressure transmitted when a quantity of liquid (as water or oil) is forced through a comparatively small orifice or through a tube. The capillary hole (34) allows retains the smallest articles that the practitioner desires to remain in the well (28) while draining reagents, washing fluids, waste fluids and the like quickly such that the other fluids may be applied, making the system more conducive to quick assay protocols (see COL. 9, lines 35-37; COL. 14, lines 20-25). Donald discloses an opening (21) from draining the eluate from the vessel (10) (see FIGS. 1, 2, 6, and 7; COL. 3, lines 44-49; COL. 4, lines 5-9). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the sample vessel of Classon et al. with the bottom extraction hole taught by both Kedar et al. and Donald to drain wastes from the insert, as disclosed by Kedar et al. and Donald.

Application/Control Number: 09/620,331

Art Unit: 1743

8. Claims 11, 17, 19, 20, 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,567,309 to Classon et al. in view of U.S. Patent No. 3,618,913 to Stevenson et al.

Page 8

Referring to claims 11 and 26, Classon et al. disclose the steps of positioning and inserting a volume-adjusting insert (12) into a sample vessel (100), positioning a penetrating sample deposit/extraction element (86) above the insert (12), and inserting the penetrating sample deposit/extraction element (86) through the septum seal (37) and conical guide (74) and into the reduced-diameter portion (76) (see FIGS. 8-10; COL. 8, lines 4-67; COL. 9, lines 1-23). The positioning and process of inserting of the insert (12) into the vessel (100) is accomplished with the sample deposit/extraction element (86) through frictional engagement of the sample deposit/extraction element (86) and septum seal (37) (see FIGS. 8-10; COL. 7, lines 41-67; COL. 8, lines 1-50; COL. 9, lines 4-23). Classon et al. do not explicitly disclose performing the steps of positioning and inserting the penetrating sample deposit/extraction element into the insert before the steps of positioning and inserting the insert into the sample vessel such that the sample deposit/extraction element is required to position and insert the insert into the vessel. Stevenson et al. disclose that the needle is positioned and inserted into insert prior to placing the insert into the vessel for the purposes of automation and efficiency. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Classon et al. to insert the needle into the insert prior to placing the insert into the vessel as in Stevenson et al. for purposes of automation and efficiency.

Application/Control Number: 09/620,331

Art Unit: 1743

Referring to claims 17, 32, Classon et al. disclose that the vessel is part of the sample handling device, such as an autosampler. Classon et al. do not explicitly disclose the sample vessel is one of a plurality of wells in a tray. However, it is very well known to use sample vessels that are part of a plurality of wells in a tray, which is suitable for automation to quickly and efficiently process multiple samples from multiple vessels. Stevenson et al. disclose an automatic sampler-injector for use in liquid chromatographic analytical procedures that takes samples from a plurality of sample containers held within a plurality of wells in a tray and injects them into the chromatographic column (see FIG. 1). The use of a plurality of wells in a tray allows for an automated sampling and injecting of a plurality of samples of consistent and accurate repetitive volumes of liquid in a column(s) (see COL. 2, lines 65-68; COL. 3, lines 22-30; COL. 4, lines 65-67; COL. 5, lines 1-55; COL. 9, lines 47-55). The system promotes efficiency. There is no lag time between sampling as the next sampling is ready to be made as soon as the turntable is advanced (see COL. 9, lines 47-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Classon et al. to provide a sample vessel that is one of a plurality of wells in a tray as in Stevenson et al. to promote sampling efficiency and consistent and accurate repetitive

Page 9

Referring to claims 19, 20, 27-30, Classon et al. disclose a single use insert detachable from the sample deposit/extraction element (see FIGS. 8-10). Classon et al. do not explicitly disclose withdrawing the insert from the vessel and positioning the insert to another processing location, particularly a second sample vessel, by frictional

injection of sampling volumes into a column(s).

engagement of the sample deposit/extraction element and septum seal. According to Merriam-Webster Collegiate Dictionary, friction is defined as force that resists relative motion between two bodies in contact, septum is defined as a dividing wall especially between bodily spaces, and seal is defined as a closure that must be broken to be opened and that thus reveals tampering or to fasten with or as if with a seal to prevent tampering or to close or make secure against access, leakage, or passage by a fastening or coating or to fix in position or close breaks in with a filling. Stevenson et al. disclose withdrawing the insert (14) from the vessel (11) and positioning the insert that is frictionally engaged or fixed in position by the walls of both the insert and sample deposit/extraction element, as they are unitary, such that forces are inherent between them that resists relative motion between the two, to another processing location, particularly another vessel (11) to process another sample (see COL. 3, lines 23-30; COL. 4, lines 21-26 and 56-68; COL. 5, lines 1-68; COL. 6, lines 1-13; COL. 9, lines 45-55). The use of a single insert for multiple vessels each with samples is economical compared to using an insert per sample which is adds up with handling large number of samples, efficient as time is not spent changing the insert, and produces more precise results with using a single insert as opposed to various inserts each with its inherent differences. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Classon et al. to withdrawn the insert from the vessel and position the insert to another processing location by frictional engagement of the sample deposit/extraction element and the septum seal as in Stevenson et al. since it is more economical to use one insert for a plurality of samples, efficient since time is not spent

Page 10

changing the insert, and produces more precise results among samples since the variability of using different inserts will not be a factor.

Referring to claim 31, Classon et al. disclose inserting the penetrating sample deposit/extraction element through the first septum seal and the conical guide and into the reduced-diameter portion. Classon et al. disclose a second septum seal in the bottom portion (see FIGS. 8-10). Classon et al. do not disclose the step of inserting the sample deposit/extraction element through the second septum seal after inserting the penetrating sample deposit/extraction element through the first septum seal and the conical guide and into the reduced-diameter portion. Stevenson et al. disclose a needle that penetrates through the first and second septum to force liquid into the needle and easily allow withdrawal of liquid from the vessel (see COL. 5, lines 42-67; COL. 6, lines 1 and 2; COL. 7, lines 1-68; COL. 8, lines 1-27). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method Classon et al. to insert the needle through the first and second septum seals as in Stevenson et al. to force liquid into the needle or easily allow withdrawal of liquid from the vessel.

9. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,567,309 to Classon et al. in view of U.S. Patent No. 6,406,671 to DiCesare et al.

Referring to claim 31, Classon et al. disclose a second septum seal in the bottom portion (see FIGS. 8-10). Classon et al. do not disclose the step of inserting the sample deposit/extraction element through the second septum seal after inserting the penetrating sample deposit/extraction element through the first septum seal and the conical guide and

Application/Control Number: 09/620,331 Page 12

Art Unit: 1743

into the reduced-diameter portion. However, it is very well known to have both ends of an insert penetrable for many reasons, such as the convenience of providing penetrable top and bottom ends of the insert with identical structural elements such that one may use either end without the additional time of flipping the insert. DiCesare et al. disclose penetrating through both septum seals either to withdraw liquid from or dispense liquid into the bottom of the container without contaminating the interior or exterior of the insert (see COL. 5, lines 56-65). This is particularly applicable since runs of filtered and non-filtered material or control and variable groups in order to compare results. Additionally, if sample liquid is not already present at the bottom of the vessel and the insert is already in place, the configuration would allow a filled syringe to penetrate through the first and second septum seals such that the filled syringe could dispense into the vessel without contaminating the interior or outer surfaces of the insert or an empty syringe could withdraw liquid from the vessel without contaminating the interior or outer surfaces of the insert. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Classon et al. to insert the sample deposit/extraction element through the first and second septum seals of the insert as in DiCesare et al. to allow penetration through both ends such that no time is spent flipping the insert for use and withdrawal liquid from or dispensation into the vessel without contaminating the interior or outer surfaces of the insert.

Response to Arguments

10. Applicant's arguments filed 1/27/2003 have been fully considered but they are not persuasive.

Applicant maintains that the claims recite novel physical features and structure and make the claim patentable, as none of the cited and relied-upon references disclose the claimed method steps. Applicant also maintains that the Classon et al. reference does not teach for suggest insertion of the needle 86 into the well 76 in a sufficient depth to provide axial alignment of the needle and device. Examiner maintains that Classon et al. do teach the method steps, including the insertion of the needle 86 into the well 76 (see COL. 9, lines 19-21). It is interesting that Applicant makes this statement in the reference characters of Classon et al. using a different embodiment of Classon et al. than the previous Office Action sent. Examiner has now used a different embodiment of Classon et al. to address the claims based on the amendments to the claims.

Page 13

Applicant maintains that Classon et al do not provide the new limitations of inserting the needle into the insert prior to placing the insert into the vessel and withdrawing the insert from the vessel. Stevenson et al. provide this limitation with the motivation of automation and efficiency. Stevenson et al. is analogous art, as both deal with similar systems in chromatography. Stevenson et al. also teach withdrawing the insert into another processing location by frictional engagement of the needle and septum, which also promotes automation and efficiency without the steps of changing the insert.

Applicant maintains that Classon et al. discloses only insertion of the cap into the vial by a structure of the sample apparatus acting against the top side of the septum.

DiCesare et al. disclose that both the top and bottom septum seals may be penetrated by the sample deposit/extraction element to access or withdraw liquid from the vessel when

the insert is already placed in the vessel. For similar reasons, Stevenson et al. also provides the limitation with motivation of forcing or allowing liquid to be easily withdrawn from the vessel.

Applicant maintains that Classon et al. do not disclose transferring a sample fluid through processing elements. Classon et al. do disclose fluid flowing through the processing element to filter out particular matter or other compounds.

Applicant maintains that references take different approaches--Kedar et al. teach a capillary hole in a vessel requiring extrinsic forces from transfer and Donald teaches a miniaturized chromatography column. Applicant maintains that there is no motivation to combine. Both Kedar et al. and Donald deal with filter, whether it is extraction or chromatography, which is directly related to the filtering and chromatographic processes of Classon et al. Classon et al. already disclose the use of hydraulic pressure generated by the needle to transport the sample fluid through the insert. Classon et al. do not disclose a bottom extraction opening. Both Kedar et al. and Donald each disclose a bottom opening. While liquid is flowing through the insert and processing element of Classon et al., the excess liquid, which is considered waste, could be drained through the bottom to prevent overflowing the insert and reduce the amount of liquid within the vessel for ease of handling. Kedar et al. do disclose that extrinsic forces are required to push the liquid through the opening. These extrinsic forces, which may be a vacuum, absorbent, etc., disrupts the tranquility of the liquid such that liquid or hydraulic force by its weight would help drain the liquid through the opening. Donald indeed teaches a chromatography column, and Classon et al. deals with chromatography. The purpose of

these secondary references is to provide the limitation of the bottom opening. Donald teaches that wastes are removed from the opening to get rid of excess liquid, which may render the process element ineffective.

Applicant disclose that the references in combination or not would not result in a process of providing alignment of a needle with the insert for insertion in a sample vessel. Classon et al. inherently provides the alignment of a needle with the insert in the process of inserting the insert further into the sample vessel. Stevenson et al. provides the the alignment of the needle with the insert such that the insert is inserted into the sample vessel via the needle.

Conclusion

- 11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They include one or more limitations in the claims.
- 12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Application/Control Number: 09/620,331 Page 16

Art Unit: 1743

however, will the statutory period for reply expire later than SIX MONTHS from the date of this

final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The

examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 872-9310 for regular

communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan

Examiner

Art Unit 1743

eq

June 19, 2003

Technology Center 1700